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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,161	09/23/2003	Kathryn F. Sykes	MCRO:002US	4356

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EXAMINER

SALIMI, ALI REZA

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,161

Applicant(s)

SYKES ET AL.

Examiner

A R. Salimi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2/10/05, 11/15/04, 11/12/04, 1/20/04, 12/22/03.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group IV (claims 32-42, within the scope of SEQ ID NOs: 5, 6, 7, and 8) in the reply filed on 10/09/2006 is acknowledged. Applicants have canceled the non-elected claims 1-31, 43-73 in reply filed on 10/09/2006.

Claim Rejections - 35 USC § 112

Claims 32-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32, 34-42 are vague and indefinite for recitation of "fragment thereof", the intended metes and bounds of the fragment is not defined. Claims have been interpreted in light of the disclosure and since the disclosure does not set forth the boundaries of fragments claims are indefinite. This affects claim 33.

Claim Rejections - 35 USC § 112

Claims 32-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for induction of immune response (antibodies only), does not reasonably provide enablement for vaccine for either entire gene, entire protein or fragment thereof which is reserved for induction of complete protective response against herpesvirus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The specification has some assertion regarding induction of antibodies which is categorized as an

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induction in immune response. However, the specification has no teaching regarding a subsequent exposure of the natural host to the virus and the level of protective immunity. In other words the specification has not shown any protective response absent undue experimentation. The state of the art does not recognize protective response, as evidence see Ghiasi et al (Archives of Virology, 1994, Vol. 138, pages 199-212, the abstract) wherein no protection were detected when gL or UL were administered.

Additionally, the scope of the claims are directed to vaccines, Applicants have general statements regarding the vaccine composition and fragment thereof to herpesvirus and induction of protective response. However with regard to an unpredictable field this does not constitute an adequate disclosure. See Fiers v. Revel, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993); and also decision by the Federal Circuit with regard to the enablement issues see Genentech Inc. v. Novo Nordisk, 108 F.3d 1361, 42 USPQ2d 1001 (Fed.Cir. 1997). For example, the CAFC stated that "It is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute enablement." (See page 1005 of the decision). In the instant case the specification does not teach or provide any guidance for development of a vaccine for herpesvirus. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation. The applicant cannot rely on the knowledge of those skilled in the art to enable the claims without providing adequate teaching. Therefore, it is concluded that in the absence of teaching by the applicants one ordinary skilled in the art would be required to conduct large quantity of experimentations to fully enable the claimed invention. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would

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be required to enable the intended claim. Many of these factors have been summarized *In re Wands*, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988). Amending the claims to an immunogenic composition would obviate this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32-36, 38-40, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Ghiasi et al (Archives of Virology, 1994, Vol. 138, pages 199-212).

The above cited art taught utilization of glycoprotein L and its activity as a composition to induce immune response against herpesvirus, gL taught by Ghiasi et al inherently encompasses the sequences that are now claimed. They taught HSV- 1 gene UL1 was isolated and inserted into an expression vector (see the abstract, and page 200, 2nd full paragraph). Mice vaccinated with baculovirus expressed gL produced serum antibodies that reacted with authentic HSV-1 gL (see the abstract). The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Moreover, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. See, Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

Claims 32-36, 38-40, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Perry et al (Journal of General Virology, 1988, Vol. 69 (Pt 11), pages 2831-2846).

The claims are directed to a product and according to the in-house sequence search the sequence Perry et al taught the same product in the above cited art (see Figure 1, and Table 1). The claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Additionally, if the prior art structure is capable of performing the intended use, then it meets the claim. See In re Otto, 136 USPQ 458, 459 (CCPA 1963). Moreover, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. See, Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

Claims 32-36, 40, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by McGeoch et al (Journal of General Virology, 1988, Vol. 69 (Pt 11), pages 1531-1574).

The claims are directed to a product and according to the in-house sequence search the sequence McGeoch et al taught the same product in the above cited art (see Table 1). The claiming of a new use, new function or unknown property, which is inherently present in the

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prior art, does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Claims 37 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Dubin (US Patent No. 5,807,557 A).

The claimed product is clearly anticipated by the claimed product taught by Dubin (see the abstract, and claim 1).

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be

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obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

11/17/2006

ALI R. SALIMI
PRIMARY EXAMINER